AVOBENZONE, HOMOSALATE, OCTISALATE, OCTOCRYLENE- avobenzone, homosalate, octisalate, octocrylene lotion
Vi-Jon, Inc

Disclaimer: Most OTC drugs are not reviewed and approved by FDA, however they may be marketed if they comply with applicable regulations and policies. FDA has not evaluated whether this product complies.

Ultra Sunscreen Lotion SPF 30 769

Active Ingredients

Avobenzone 3%

Homosalate 10%

Octisalate 5%

Octocrylene 10%

Purpose

Sunscreen

Uses

- helps prevent sunburn
- if used as directed with other sun protections measures (see ***Directions***), decreases the rist of skin cancer and early skin aging caused by the sun

Warnings

For external use only

Do not use

- on damaged or broken skin

When using this product

- keep out of eyes. Rinse with water to remove

Stop use and ask a doctor if

- rash occurs

Keep out of reach of children.

If swallowed, get medical help or contact a Poison Control Center right away

Directions

- apply liberally 15 minutes before sun exposure
- reapply:
- after 80 minutes of swimming or sweating
- immediately after towel drying

- at least every 2 hours
- **Sun Protection Measures.** Spending time in the sun increases your risk of skin cancer and early skin aging. To decrease this risk, regularly use a sunscreen with a Broad Spectrum SPF value of 15 or higher and other sun protection measures including:
- limit time in the sun, especially from 10 a.m. - 2 p.m.
- wear long-sleeved shirts, pants, hats and sunglasses
- children under 6 months of age: Ask a doctor

Other Information

- Protect the product from excessive heat and direct sun

Inactive ingredients

water, ethylhexyl palmitate, sorbitol, polyamide-8, benzyl alcohol, tocopherol, caprylic/capric triglyceride, triethanolamine, fragrance, acrylates/C10-30 alkyl acrylate crosspolymer, chlorphenesin, sodium ascorbyl phosphate, olethe-3, disodium EDTA

disclaimer

May stain or damage some fabrics or surfaces

Oxybenzone & Octinoxate free

This product is not manufactured or distributed by Bayer, distributor of Coppertone Ultra GUARD Sunscreen Lotion Broad Spectrum SPF 30.

Manufactured by: Vi-Jon, Inc, 8515 Page Ave, St. Louis, MO 63114

Adverse Reactions

Manufactured by: Vi-Jon, Inc., St. Louis, MO 63114

Questions or Comments? 1-888-593-0593

principal display panel

mountain

falls

*Compare

to Dawn

tough

on

grease

ultra

concentrated

cleaning

power

dish soap

antibacterial hand soap

orange scent

8 FL OZ (236 mL)

princpal display panel

SPF 30

SOLAR SCREEN

ULTRA

SUNSCREEN

LOTION

Broad Spectrum SPF 30

Water Resistant (80 minutes)

Hypoallergenic

Reef Friendly Formula

Compare to Coppertone

Ultra Guard Sunscreen Loton

8 FL OZ (236 mL)

AVOBENZONE, HOMOSALATE, OCTISALATE, OCTOCRYLENE

avobenzone, homosalate, octisalate, octocrylene lotion

Product Information			

Product Type	HUMAN OTC DRUG	**Item Code (Source)**	NDC:0869-0769
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
AVOBENZONE (UNII: G63QQF2NOX) (AVOBENZONE - UNII:G63QQF2NOX)	AVOBENZONE	30.3 mg in 1 mL
HOMOSALATE (UNII: V06SV4M95S) (HOMOSALATE - UNII:V06SV4M95S)	HOMOSALATE	101 mg in 1 mL
OCTISALATE (UNII: 4X49Y0596W) (OCTISALATE - UNII:4X49Y0596W)	OCTISALATE	30.3 mg in 1 mL

Inactive Ingredients

Ingredient Name	Strength
water (UNII: 059QF0KO0R)	
ETHYLHEXYL PALMITATE (UNII: 2865993309)	
SORBITOL (UNII: 506T60A25R)	
POLYAMIDE-8 (4500 MW) (UNII: 77723GV81A)	
BENZYL ALCOHOL (UNII: LKG8494WBH)	
TOCOPHEROL (UNII: R0ZB2556P8)	
MEDIUM-CHAIN TRIGLYCERIDES (UNII: C9H2L21V7U)	
TROLAMINE (UNII: 9O3K93S3TK)	
CARBOMER INTERPOLYMER TYPE A (ALLYL SUCROSE CROSSLINKED) (UNII: 59TL3WG5CO)	
CHLORPHENESIN (UNII: I670DAL4SZ)	
SODIUM ASCORBYL PHOSPHATE (UNII: 836SJG51DR)	
OLETH-3 (UNII: BQZ26235UC)	
EDETATE DISODIUM ANHYDROUS (UNII: 8NLQ36F6MM)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:0869-0769-34	236 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	01/12/2016	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph final	part352	01/12/2016	

Labeler - Vi-Jon, Inc (790752542)

Registrant - Vi-Jon, Inc (790752542)

Establishment

Name	Address	ID/FEI	Business Operations
Vi-Jon, Inc		790752542	manufacture(0869-0769)